Starfix lead extraction: Clinical experience and technical issues

TITLE PAGE

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ABSTRACT

Transvenous lead extraction (TLE) of the Starfix coronary sinus (CS) active-fixation lead may be challenging, due to undeployment of fixation lobes and venous occlusion. We report our experience in Starfix TLE, in comparison with previous data.

A 78-year-old male, implanted in 2009 with Starfix lead, was referred to our institution for TLE, due to infective endocarditis with lead-associated vegetations. The tip of Starfix lead was located in distant, anterior position, in the Great Cardiac Vein, close to patent LIMA-to-LAD anastomosis, and first-choice surgical removal had a prohibitive operative risk.

Conventional dilatation beyond CS os, as well as the use of a standard delivery catheter, was ineffective. An off-label modification of the delivery, by cutting the distal soft tip, was successful. However, the tip of the lead fragmented and was trapped in the innominate vein. Then a gooseneck snare grasped the fragment, allowing complete retrieval.

TLE of Starfix leads may be particularly challenging, especially when its tip is located in a distant anterior location. In these cases, important help may be obtained by dilatation within the CS, by means of conventional or modified delivery catheters. Only experienced operators, sometimes with non-conventional techniques, should perform TLE of Starfix leads.

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LEARNING OBJECTIVE

TLE of Starfix leads may be challenging, particularly when the tip is located in a distant anterior position. Dilatation with conventional tools may be precluded. In these cases modifications of the delivery catheters may be useful. Surgery should be avoided as first-choice procedure; only experienced operators, sometimes with non-conventional techniques, should perform TLE of Starfix leads.

Learning objective word count: 56

INTRODUCTION

Implantation of left ventricular (LV) leads through coronary sinus (CS) may be challenging. Dislodgements of LV leads accounts for 4[1]-10% of cases,[2-5] with threshold worsening, loss of capture, phrenic nerve stimulation and inadequate cardiac resynchronization therapy (CRT). Technology improvements, like preformed shapes of LV leads, were developed to maintain adequate stability. Even more, active fixation leads were introduced (Attain Starfix OTW LV Lead, Model 4195, Medtronic, Minneapolis, MN, USA). First experience with such leads was reported in 2007,[6] with only 0.7% dislodgement rates at two-year follow-up,[7] and improved success rate of CRT.[8] However, the difficulty of using such LV active fixation leads was confirmed, particularly with respect to transvenous lead extraction (TLE),[9] even in recently implanted leads.[6, 7]

CASE REPORT

A 78-year-old male patient was referred to our institution for TLE, due to pocket infection with lead-associated vegetations.

Clinical history.

In 1991 the patient suffered an inferior myocardial infarction, and the same year he underwent surgical revascularization with left internal mammary artery (LIMA) anastomisation to left anterior descending (LAD). In 2009, due to depressed ejection fraction with inducible ventricular tachycardia at electrophysiological study, the patient was implanted at another centre with a single chamber ICD; a double coil passive fixation shock lead was used (Sprint Quattro, Model 6944, Medtronic Inc., Minneapolis, MN, USA). From January 2011 the patient experienced relapsing skin dehiscence at the generator pocket, with exposure of the can and lead. The absence of systemic involvement was accepted, by the referring physicians

and in contrast to Expert Consensus,[10] as warranting repeated two local repair procedures, with deep relocation of the exposed lead and pulse generator, and one generator replacement with preservation of the lead. Even so, due to worsened heart failure with left bundle branch block, the device was upgraded to a biventricular system in November 2011. Permanent low-rate atrial fibrillation led to implantation of a new LV lead only. Lateral and postero-lateral CS branches were not suitable for implantation, and stability issues resulted in the choice of an active fixation lead (Attain Starfix LV OTW Lead, Model 4195, Medtronic Inc.), which was anteriorly located in the mid-portion of the great cardiac vein (GCV). A biventricular device (Concerto II CRTD D 294 TRK, Medtronic) was implanted, with the atrial port capped. The procedure was complicated by pocket hematoma, requiring surgical revision one month later. On June 2014, new skin erosion was evident, with further exposure of one lead. A transoesophageal echocardiography disclosed lead-associated filiform images, along the transatrial segment of both right ventricular shock and LV CS lead, finally and clearly convincing the colleagues of the need of TLE.

Patient evaluation and diagnostic work-up.

After admission to our centre, control coronary angiography showed proximal occlusion of the LAD, Circumflex and Right coronary arteries, with myocardial perfusion due completely to a patent LIMA-to-LAD anastomosis. Myocardial perfusion with 99Tcm-methoxyisobutylisonitrile (MIBI) stress/rest SPECT disclosed a wide irreversible inferior and infero-lateral defect, and a small partially reversible apical defect. Therefore, the only viable myocardial tissue was that located in the anterior position, perfused through the above-mentioned LIMA-to-LAD graft.

Cardiac surgeons ruled out surgical lead extraction as first-choice procedure, due to expected difficulty and risk of removing a lead implanted in close proximity with a working LIMA-to-LAD anastomosis (Figure 1, Panel A; **Video 1**).

Transvenous lead extraction.

TLE was performed under local anaesthesia in the Electrophysiology Lab, with a cardiac surgery team on active duty and with support of an Anaesthesiologist and with working anaesthesia equipment in the room. We used manual traction with conventional and locking stylets, and dilation with polypropylene sheaths (Cook Vascular Inc., Leechburg, PA, USA). The size of the sheaths, all provided with bevelled ends, ranged from 7 to 11.5 French. We used the single-sheath technique described by Bongiorni,[11] and counter-traction.

First, the Sprint Quattro lead was extracted with conventional polypropylene Byrd mechanical dilators (Cook Vascular Inc.), up to the 11.5-French inner XL ñwhiteò one (Figure 1, Panel B; **Video 2**). A subsequent selective retrograde CS venography disclosed an occlusion at the mid portion of the main CS (Figure 1, Panels C and D). A 0.014ò Hi-Torque Balance Middleweight guide (Abbott Vascular, Santa Clara, CA, USA), inserted through the Swan-Ganz lumen, was able to gain access to the distal CS (Figure 1, Panels E and F; **Video 3**). The LV led was cut as usual, and a long standard CS stylet (Model 6054, 0.016ò, 110 cm, Medtronic) was inserted and secured with ties. Advancing the push tubing of the Starfix along the lead body resulted in a partial undeployment of the proximal lobes only. A manual traction attempt was ineffective; therefore, dilatation was performed along the LV lead using the inner 7.0-French and 8.5-French XL Byrd dilators, with the bevel stopping immediately after CS entrance (Figure 1, Panel G; **Video 4**). A 57-cm long 7-French CS delivery (Attain Command CS Cannulation Catheter, Model 6250VI-57S, Medtronic) was advanced over the LV lead near the origin of the GCV (figure 1, Panels H and I; and Figure 2, Panels A to D; **Video 5**). Then, as previously described,[12] the soft tip collar of the delivery was cut, in order to produce a greater pushing force along the lead. This off-label modified delivery was able to reach the proximal series of the fixation lobes, resulting in their further undeployment (Figure 2, Panels E to H; **Video 6**). The distal end of this modified delivery was firmly anchored to

the proximal lobes, allowing repeated traction to be effective in extracting the lead from the CS (Figure 2, Panel I; **Video 7**). The tip of the Starfix lead, with its distal fixation lobes deployed, not protected inside a dilator, was trapped in the proximal innominate vein, immediately before the costo-clavicular angle narrowing (Figure 3, Panel A). Manual traction resulted in fragmentation of the lead, with its tip retained, and consequent occlusion of the vein (figure 3, Panel B). A Lassos snare catheter, 90° loop angle, 30 mm loop diameter (OSYPKA AG, D-79618 Rheinfelden-Herten, Germany) was unsuccessful in catching the lead fragment (Figure 3, Panel C). A 0.025ò J Tip PTFE guide wire (Medtronic Inc.), driven by a 7-French MPA 1 guiding catheter (Cordis Corp., Miami Lakes, FL, USA), could pass through the occlusion, and the lead tip was partially freed (Figure 3, Panel D). An Amplatz Goose Neck 6-French snare catheter, with a 30mm loop snare (ev3 Inc., Plymouth, MN, USA), was then used to grasp the tip (Figure 3, Panels E to G), thereby allowing complete retrieval of the tip fragment through a 18-french long femoral sheath (Cook Vascular)(Figure 3, Panels H and G; **Video 8**). Subsequent course was uneventful. Particularly, no pericardial effusion was observed.

DISCUSSION

The extraction of the Attain Starfix lead clearly can be particularly challenging, even with recently implanted leads (within 4 weeks).[6] Previous experiences of Starfix TLE are reported in Table 1, with regard to dwelling time, implant site, undeployment of fixation lobes, technique used and progression of sheaths within the main CS, beyond CS entrance, or its branches. Only cases with intention-to-treat indication to TLE were considered, while repositioning and implant revisions were not taken into account. Moreover, TLE was defined according to HRS Expert Consensus.[10] Dwelling time of extracted Starfix leads was 599,1±271.1 days (range 69 to 1029). The Starfix tip, as referred by the Authors or as could

have been gathered from the analysis of the published images, was located in a posterolateral, lateral or anterolateral position. The bevel of the dilators could reach the main CS in 15 out of 19 patients, where information could be have been gained, and a CS branch only in 7. Undeployment of fixation lobes was frequently prevented, [7, 13-16] often occurring only with proximal ones.[12-14] Such a mechanism may be responsible for acute failures in extracting leads, while chronically venous occlusion, due to reduction and slowing of blood flow with consequent thrombosis,[17] may collaborate with worsening effect. Success rate for Starfix TLE is approximately 73%, clearly below the 96-98% reported rate for intracardiac conventional[18] and passive fixation CS leads.[19]

Our described case confirms some key points about TLE of the Starfix lead: the undeployment of fixation lobes, the venous occlusion (in our case affecting the main middle CS, not just the collateral venous branches), the impossibility of conventional mechanical dilatation just beyond CS entrance, and the effectiveness of dilatation within the CS by means of conventional and/or modified CS delivery catheters.

To the best of our knowledge, with respect to published data, some features of this case are unique and should be highlighted.

The dwelling time of the Starfix lead was 988 days, well beyond the majority of extracted case (only one cases of the Cleveland population was implanted as long as 1029 days).[13] Our patient is the only one in which the Starfix lead was located in an anterior position, in the mid portion of the GCV. Such a distant location increases the difficulty of reaching the distal tip and performing dilatation along the lead. The progression of sheaths is even more difficult, due to the wide and almost complete curve along the main CS, and the narrow distal angulation of the vein where it reaches the interventricular groove.

Our case is the first one in which the tip of the Starfix lead is located in close proximity to a patent coronary artery anastomosis. Our surgeons refused elective surgical removal of the tip,

because of its risky location, of the redo procedure, with presumably tough dissection of old adherences surrounding the heart, and of high surgical risk of the patient. In other cases, failure of transvenous extraction of the Starfix lead was treated by urgent surgical intervention.[15] In our patient, a surgical emergency procedure would have been prohibitive.

Conclusions.

Starfix lead extraction may be challenging due to the impossibility of undeployment of fixation lobes, with increasing difficulty for the frequently observed venous occlusion around the fixation mechanism. However, some important help may be obtained by dilatation within the CS, by means of conventional or modified delivery catheters. This approach must always be attempted, even in presumably difficult cases, due to the long dwelling time, unfavourable and distant anatomic location, and prohibitive surgical risk.

Conflict of interest. None to declare.

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FIGURE LEGENDS

Figure 1.

Panel A: coronary angiography, showing a patent LIMA-to-LAD anastomosis in the interventricular grove, in close proximity to the tip of the Starfix lead. Circumflex and right coronary arteries are occluded, with myocardial perfusion entirely depending on this working anastomosis. Panel B: ICD shock lead extraction, with standard polypropylene Byrd dilators. Panel C and D: selective retrograde CS venography. The mid portion of the main CS, just beyond the inflated Swan-Ganz catheter balloon, is occluded. Panel E and F: a 0.014ò Hi-Torque BMW guide, inserted through the Swan-Ganz lumen, gains access to distal CS.

Panel G: advancing the push tubing of the Starfix along the lead body results in a partial undeployment of the proximal lobes only. Therefore, dilatation along the LV lead is needed, using the inner 7.0-French XL Byrd dilator, with the bevel stopping immediately after CS entrance. Mechanical dilatation cannot progress just beyond CS os. Panel H and I: a 57-cm long 7-French CS delivery (Attain Command CS Cannulation Catheter, Model 6250VI-57S, Medtronic) is advanced over the LV lead into the mid portion off the main CS.

Figure 2

Panel A to C: further progression of the delivery into the CS. Panel D: the distal portion of the main CS is reached, just before the origin of the GCV in the interventricular grove.

Panel E: off-label modification of the delivery, by cutting the soft distal collar of the catheter. The modification produces a greater pushing force along the lead, so reaching the origin of the GCV. Panel F to H: the distal end of this modified delivery is firmly anchored to the proximal lobes. Panel I: extraction.

Figure 3

Panel A: during extraction, the tip of the Starfix, not protected inside a dilator, is trapped into the innominate vein, just before the costo-clavicular angle narrowing. Panel B: manual traction results in fragmentation of the lead, with its tip retained. Due to the traction forces carried out, the fixation lobes are forced against the vessel wall, and again fully deployed, so causing venous occlusion. Panel C: a Lassos snare catheter, 90° loop angle, 30 mm loop diameter is unsuccessful in catching the lead fragment. Panel D: a 0.025ò J Tip PTFE guide wire (Medtronic Inc.), driven by a 7-French MPA 1 guiding catheter (Cordis Corp., Miami Lakes, FL, USA), can pass through the occlusion, so allowing a selective venography, confirming the occlusion. As a consequence of these manoeuvres, the lead tip is partially freed. Panel E and F: an Amplatz Goose Neck 6-French snare catheter, with a 30mm loop snare (ev3 Inc., Plymouth, MN, USA) catches the tip of the Starfix lead. Panel G: the traction over the tip undeploys the lobes, as can be see at the mid innominate vein level. Panel H and I: the tip fragment of the Starfix lead is extracted through a long 18-French femoral sheath.